

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bachmann et al.

Appl. No. 10/617,876

Filed: July 14, 2003

For: Molecular Antigen Arrays Confirmation No.: 4797

Art Unit:

1648

Examiner:

Mosher, Mary.

Atty. Docket: 1700.03100001/BJD/SJE

## Declaration of Martin F. Bachmann Under 37 C.F.R. § 1.132

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

I, the undersigned, Martin F. Bachmann, declare and state as follows:

- 1. I am a co-inventor of the subject matter of U.S. Application Serial No. 10/617,876 ("the present application"), filed July 14, 2003, which is referenced above.
- 2. I am also Chief Scientific Officer at Cytos Biotechnology AG, the assignee of the present application by virtue of an assignment executed by the inventors named in the present application that was executed on October 31, November 6 and November 10, 2003.
- 3. I have reviewed and am familiar with the Office Action dated June 24, 2005, issued by the U.S. Patent and Trademark Office in the present application.
- 4. In the Office Action at page 4, line 20 to page 5, line 1, the Examiner has asserted that:

alteration of coat protein structure has unpredictable effects upon the ability to form a particle, and there is no evidence on this record that SEQ ID NO:3 is able to form a particle. If it cannot, then the specification does not teach any method of use for the protein or its coding sequence.

السرع وأبير

- 5. I, or others working under my supervision, have prepared virus-like particles (VLPs) from proteins having the amino acid sequence set forth in SEQ ID NO: 3. To prepare these VLPs, *E. coli* was transformed with plasmid pAP281-32 of Example 1, and cultured as described in Example 2. *E.coli* lysate was prepared essentially as described in Example 2, with the slight modification that lysozyme was used in the lysis buffer, and the cells subjected to three freeze-thaw cycles instead of sonication, an alternative well-known to a person of ordinary skill in the art. The lysate was then examined by electron microscopy using standard methods.
- 6. The attached Figure A shows an electron micrograph of virus-like particles formed from proteins having the amino acid of SEQ ID NO:3, using the methods referenced in paragraph 5 herein. The abundant capsids of shape indistinguishable from AP205 bacteriophage obtained in the lysate of *E. coli* expressing AP205 coat protein of SEQ ID No: 3 demonstrates that the mutation in the capsid protein does not interfere with assembly of the particles in *E. coli*. The abundant and regularly shaped capsids obtained in the lysate and shown in Figure A thus demonstrate that AP205 coat protein of SEQ ID No:3 assembles in *E. coli* to VLPs.
- 7. Therefore, a protein having the amino acid of SEQ ID NO:3 is able to form virus-like particles, confirming the disclosure of the same in the present application, e.g. at paragraph [0010].
- 8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and

Bachmann *et al.* Appl. No. 10/617,876

- 3 -

the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the present patent application or any patent issued thereon.

Further, declarant sayeth not.

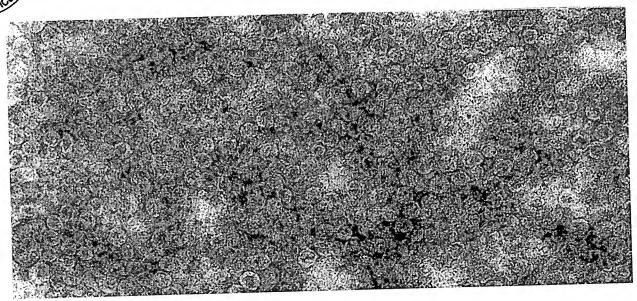
21.11.05

Date

Martin F. Bachmann



Figure A



Virus-like particles of AP205 coat protein of SEQ ID No: 3 in E. coli lysate.